

-1-

Date: 3-26-01Express Mail Label No. EL 552578668 US

Inventors:

Paul C. Harris and Brian G. Richards

Attorney's Docket No.:

2065.2001-000

COPY

COMPENSATION FOR VARIABILITY IN SPECIFIC BINDING IN QUANTITATIVE ASSAYS

BACKGROUND OF THE INVENTION

Quantitative analysis of cells and analytes in fluid samples, particularly bodily fluid samples, often provides critical diagnostic and treatment information for physicians and patients. Quantitative immunoassays utilize the specificity of the antigen (Ag) - antibody (Ab) reaction to detect and quantitate the amount of an Ag or Ab in a sample. In solid phase immunoassays, one reagent (e.g., the Ag or Ab) is attached to a solid surface, facilitating separation of bound reagents or analytes from free reagents or analytes. The solid phase is exposed to a sample containing the analyte, which binds to its Ag or Ab; the extent of this binding is quantitated to provide a measure of the analyte concentration in the sample. Transduction of the binding event into a measurable signal, however, is affected by a number of interferences, such as variability in binding of components of the assay, which are not associated with the presence or amount of the analyte. These interferences limit the specificity and applicability of quantitative immunoassays.

SUMMARY OF THE INVENTION

The invention relates to methods of measuring the amount of an analyte of interest in a fluid sample, using a solid phase assay such as a quantitative